Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte BERNARD BEER
and JOSEPH W. EPSTEIN

_____

Appeal No. 1997-1849
Application 08/414,180

_____

ON BRIEF

_____

Before WINTERS, WILLIAM F. SMITH, and LORIN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

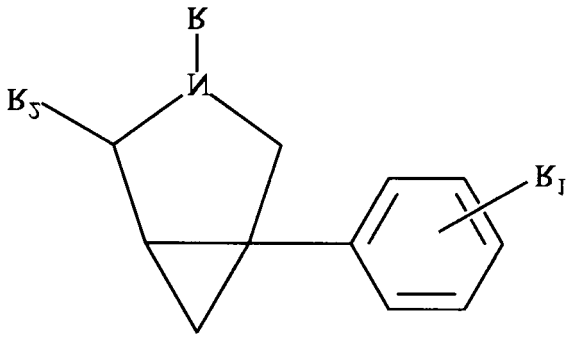
DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 28 through 45 and 47 through 50. Claims 51 and 52, which are the only other claims remaining in the application, stand allowed.

THE INVENTION

Applicants' invention relates to a method for treating a human or animal suffering from chemical dependence on alcohol or cocaine. Claims 49 and 50, which are illustrative of the subject matter on appeal, read as follows:

49. A method for treatment of an addictive, compulsive disorder caused by alcohol or cocaine abuse, which comprises the administration to a human or animal suffering from such a disorder, an effective amount of the compound of the formula:



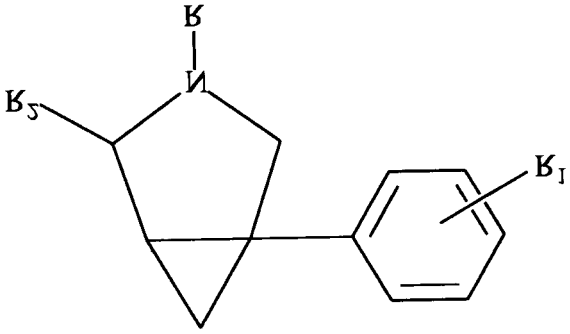
in which R is hydrogen or alkyl of 1 - 6 carbon atoms;

R^1 is hydrogen or one or two substituents selected from the halogens, alkoxy of 1 to 3 carbon atoms, CF_3 or alkyl of 1 - 6 carbon atoms; and

R^2 is hydrogen, methyl or ethyl;

or a pharmaceutically acceptable salt thereof.

50. A method for treatment of drug dependence caused by alcohol or cocaine abuse, which comprises administering to a human or animal suffering from or dependent on a drug, an effective amount of the compound of the formula:



in which R is hydrogen or alkyl of 1 - 6 carbon atoms;

R^1 is hydrogen or one or two substituents selected from the halogens, alkoxy of 1 to 3 carbon atoms, CF_3 or alkyl of 1 - 6 carbon atoms; and

R^2 is hydrogen, methyl or ethyl;

or a pharmaceutically acceptable salt thereof.

REFERENCE CITATION

In responding to the examiner's rejection under 35 U.S.C. § 112, first paragraph,

applicants rely on the following reference:

Amit et al. (Amit), “Serotonin Uptake Inhibitors: Effects on Motivated Consummatory Behaviors,” J. Clin. Psychiatry, Vol. 52, No. 12 (Suppl.), pp. 55-60 (Dec. 1991).

THE ISSUE

The issue presented for review is whether the examiner erred in rejecting claims 28 through 45 and 47 through 50 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure. More specifically, the question arises under the "how to use" requirement of 35 U.S.C. § 112, first paragraph, i.e., whether the examiner erred in concluding that the instant specification would not have enabled any person skilled in the art to use the claimed invention throughout its scope without undue experimentation.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) applicants' Appeal Brief (Paper No. 20), including the Epstein Declaration filed under the provisions of 37 CFR § 1.132 and the above-cited Amit reference, attached thereto; and (3) the Examiner's Answer (Paper No. 21).

On consideration of the record, including the above-listed materials, we reverse the examiner's rejection.

DISCUSSION

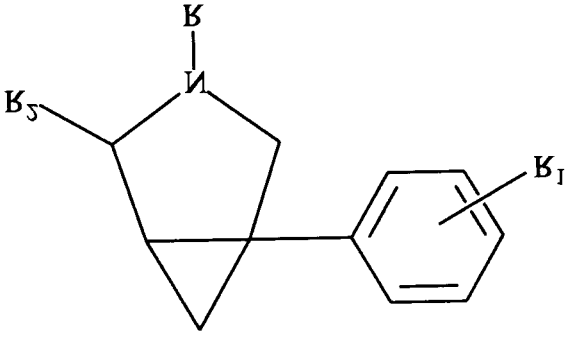
According to the examiner, the instant specification would not have enabled any person skilled in the art to use the claimed invention throughout its scope without undue experimentation. We disagree.

First, the examiner misapprehends the rather limited scope of applicants' claims. Independent claim 49 is drawn to a method for treating an addictive, compulsive disorder caused by alcohol or cocaine abuse, by administering to a human or animal suffering from such disorder, an effective amount of a specified 1-(substituted-phenyl)-3-azabicyclo[3.1.0]hexane. Likewise, independent claim 50 is drawn to a method for treating drug dependence caused by alcohol or cocaine abuse, by administering to a human or animal suffering from or dependent on a drug, an effective amount of a specified 1-(substituted-phenyl)-3-azabicyclo[3.1.0]hexane. The examiner incorrectly characterizes these claims as though drawn to methods for treating substance addiction or drug dependence or substance abuse in general (Examiner's Answer, page 3, first full paragraph). They are not. As stated in the Appeal Brief, page 2, first paragraph, and as reflected in the independent claims, applicants' invention relates to a method for treating a human or animal suffering from chemical dependence on alcohol or cocaine.

Second, it does not appear that the examiner has a quarrel with applicants' claims to the extent that they read on (1) a method for treating an addictive, compulsive disorder

caused by alcohol abuse, or (2) a method for treating drug dependence caused by alcohol abuse. In this regard, we invite attention to allowed claim 51, which reads as follows:

51. A method for treatment of an addictive, compulsive disorder caused by alcohol abuse, which comprises the administration to a human or animal suffering from such a disorder, an effective amount of the compound of the formula:



in which R is hydrogen or alkyl of 1 - 6 carbon atoms;

R^1 is hydrogen or one or two substituents selected from the halogens, alkoxy of 1 to 3 carbon atoms, CF_3 or alkyl of 1 - 6 carbon atoms; and

R^2 is hydrogen, methyl or ethyl;

or a pharmaceutically acceptable salt thereof.

We also invite attention to the Examiner's Answer, page 4, lines 4 through 6, where the examiner notes that “testing in the specification relates in large part to alcohol dependence treatment.” As best understood, the examiner's position is that the appealed claims are

based on a non-enabling disclosure to the extent that they read on (1) a method for treating an addictive, compulsive disorder caused by cocaine abuse, or (2) a method for treating drug dependence caused by cocaine abuse.

Third, a patent specification is directed not to the layman, but rather to a person having ordinary skill in the art. In re Folkers, 344 F.2d 970, 975-76, 145 USPQ 390, 394 (CCPA 1965). A specification need not teach, and preferably omits, what is well-known in the art. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (1986), cert. denied, 480 U.S. 947 (1987). Here, specification testing establishes the capability of representative 1-(substituted-phenyl)-3-azabicyclo-[3.1.0]hexanes to inhibit the neuronal reuptake of 5-serotonin, norepinephrine, and dopamine in rat brain crude synaptosomal preparations at concentrations consistent with the ability to serve as agents for treating addictive behaviors such as cocaine abuse (specification, pages 24 through 26). Given the results of that testing, persons having ordinary skill in the art would not doubt the objective truth of statements in applicants' specification that 1-(substituted-phenyl)-3-azabicyclo[3.1.0]hexanes not only attenuate voluntary ethanol consumption in rats and humans but also serve as agents for treating addictive behavior such as cocaine abuse. See the Amit reference, attached to applicants' Appeal Brief, suggesting that the effects of 5-HT(serotonin) uptake inhibitors are global in nature and not specific to any single consummatory behavior.

Fourth, it is incumbent on the PTO, whenever a rejection based on the enablement requirement of 35 U.S.C. § 112, first paragraph, is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning inconsistent with the contested statement. This the examiner has not done. For reasons already discussed, we believe that the evidence of record is consistent with statements in applicants' specification respecting how to use 1-substituted-phenyl-3-azabicyclo[3.1.0]hexanes for treating a human or animal suffering from chemical dependence on alcohol or cocaine.

Fifth, the Epstein Declaration, attached to applicants' Appeal Brief, establishes with the locomotor activity test that 1-(4-methylphenyl)-3-azabicyclo[3.1.0]hexane hydrochloride shows full antagonism of the stimulant effects of cocaine at 20-25 mg/kg, and has an AD_{50} of 7.65 mg/kg. The compound 1-(3,4-dichlorophenyl)-3-azabicyclo-[3.1.0]hexane hydrochloride shows similar effects, although it is not as potent. Both sets of data constitute evidence of the effective treatment of cocaine abuse, and how to use representative 1-(substituted-phenyl)-3-azabicyclo[3.1.0]hexanes, consistent with the disclosure set forth in applicants' specification.

Sixth, in the specification, pages 26-28, applicants describe how to use their 1-(substituted-phenyl)-3-azabicyclo[3.1.0]-hexanes, including specific modes of administration, dosages, and preparation of dosage forms. All in all, we have no doubt

that ample knowledge, including description of procedures, materials, and suitable concentrations, has been imparted to persons having ordinary skill in the art, enabling them to practice the claimed method throughout its scope without undue experimentation.

The examiner's decision, rejecting claims 28 through 45 and 47 through 50 under 35 U.S.C. § 112, first paragraph, is reversed.

REVERSED

Sherman D. Winters Administrative Patent Judge	)
	) BOARD OF PATENT
William F. Smith Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
Hubert C. Lorin Administrative Patent Judge	)

SDW /cam

Ronald W. Alice
AMERICAN HOME PRODUCTS CORP.
Patent Law Dept. 2-B
One Campus Drive
Parsipany, NJ 07054